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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/525,558

09/02/2005

Jorg Hacker

H&U122

9541

7590

12/23/2008

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EXAMINER

JOIKE, MICHELE K

ART UNIT

PAPER NUMBER

1636

MAIL DATE

DELIVERY MODE

12/23/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/525,558	Applicant(s) HACKER ET AL.	
	Examiner MICHELE K. JOIKE	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of a reply to the previous Office Action, filed October 1, 2008. Claims 1-6 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, mailed April 30, 2008 that is not addressed in this action has been withdrawn.

Because this Office Action only maintains rejections set forth in the previous Office Action and/or sets forth new rejections that are necessitated by amendment, this Office Action is made FINAL.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Blum-Oehler et al in view of Trevors et al.

Claims 2-6 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Uraji et al in view of Blum-Oehler et al, in view of Trevors et al, and in further view of Alexeyev et al.

Response to Arguments Concerning Claim Rejections – 35 USC § 103 (a)

Applicant's arguments filed October 1, 2008 have been fully considered but they are not persuasive.

The following grounds of traversal are presented:

As would be understood by someone having ordinary skill in this art, the general methodologies described by Trevor et al would not have been useful to remove the two plasmids in E. coli strain DSM 6601. The inventors discovered that the elimination of the two plasmids must take place in multiple steps, and that some of the steps must be carried out in parallel.

Uraji deals with Agrobacterium. Agrobacterium and E. coli are two completely different organisms, and the removal or even desirability of removal of the plasmids would not be viewed by someone having ordinary skill in this art as being equivalent or even suggestive of each other. Furthermore, simply changing the order of the culture mediums with the order selected in the application would not be obvious or successful.

Alexeyev et al. teach the introduction of a tetracycline-resistant cassette, but it is not described for E. coli strain DSM 6601. Also, our particular combination of steps leading to a plasmid-free DSM 6601 strain, as set forth in claims 2-6, is not mentioned at all.

Lastly, Schultz et al show that a foreign plasmid was not stable in vivo. Manipulation of DSM 6601/Nissle 1917 to alter its plasmid content had limited success in Schultz et al. We submit this paper to show that, even as late as

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2005, the construction of a plasmid-free DSM 6601 derivative is not a routine or obvious matter.

Applicant's arguments have not been found persuasive for the following reasons.

Applicants are asserting that the methods to cure bacteria of plasmids, as taught by Trevor, would not be useful for DSM 6601. However, this assertion is unsupported by any evidence. Also, "useful" is a vague term. Are Applicants stating that the methods in Trevor would not work? Also, the claims do not recite that the elimination of the two plasmids must take place in multiple steps, or that some of the steps must be carried out in parallel.

Uraji teaches a curing method. There is no indication that this method would not work in other bacteria, and Agrobacteria are gram negative bacteria, like E. coli. Also, there is no specified order to the steps, so there is no changing of the order.

Alexeyev was used to teach use of a tetracycline cassette in a plasmid, not to teach a combination of steps leading to a plasmid-free DSM 6601 strain, or the strain itself. When combined with Blum-Oehler, Trevor and Uraji, the method is taught.

Schultz et al do not teach curing a bacterium of plasmids. Also, they introduce a foreign plasmid. They do not teach using the endogenous plasmids like Blum-Oehler do, therefore the fact that introducing a foreign plasmid into DSM 6601 is irrelevant.

Allowable Subject Matter

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **MICHELE K. JOIKE** whose telephone number is (571)272-5915. The examiner can normally be reached on M-F, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michele K Joike
Examiner
Art Unit 1636

/David Guzo/
Primary Examiner
Art Unit 1636